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IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

On Writ of Certiorari to the United States
Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE
VENTRITEX, INC.
IN SUPPORT OF RESPONDENT

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INTEREST OF AMICUS CURIAE

Ventrifex, Inc. has obtained letters from both Petitioner and Respondent consenting to the filing of this *amicus* brief supporting Respondent. The letters have been filed with the Clerk.

Amicus Ventrifex, Inc. is the manufacturer of an implantable defibrillator that is presently being clinically tested pursuant to an investigational device exemption (IDE) from the Food and Drug Administration. Ventrifex's defibrillators were not manufactured or implanted until the original seventeen-year period of Eli Lilly's '757 patent had expired and the patent was in its extended term.¹

Ventrifex was founded in 1985 through financing via private placement. Ventrifex is composed of a number of individuals who are experts in the medical device field, and were previously employed in similar medical device endeavors. Since the founding of Ventrifex, over 15 million dollars has been invested in the company. An additional five million dollars is presently being sought via private placement for use in manufacturing defibrillators for the clinical trials and for conducting the clinical trials. All of the investment in Ventrifex to date relates to the research and development of its improved implantable defibrillator which is now in clinical trials.

Ventrifex's implantable defibrillator is superior in numerous respects to the implantable defibrillator currently marketed by Eli Lilly's subsidiary CPI. However, Petitioner Eli Lilly would have this Court construe 35 U.S.C. § 271(e)(1) in a manner that will prevent Ventrifex from clinically testing

¹ The Lilly '757 patent issued October 26, 1971 and normally would have expired on October 26, 1988. The patent term was extended to October 26, 1990 pursuant to 35 U.S.C. § 156. The first implantation of the Ventrifex defibrillator occurred in July, 1989.

its implantable defibrillator until the extended period of Eli Lilly's patent has terminated.

Ventritex, Inc., a company that was formed for the purpose of developing a lifesaving medical device, is in a unique position to provide this Court with a realistic picture of how the proper interpretation of section 271(e), i.e., the Federal Circuit's construction of section 271(e)(1), stimulates innovation regarding improved medical devices. Ventritex is also in a strong position to demonstrate the fallacy inherent in Petitioner's argument that a medical device must be distinguished from a drug when construing section 271(e). Ventritex will demonstrate that no logical reason exists to distinguish between an improved medical device and an improved drug.

SUMMARY OF THE ARGUMENT

This case presents to this Court the construction of 35 U.S.C. § 271(e)(1), a statute which immunizes from patent infringement the making, using or selling of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (1988). The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, is clearly a law which regulates the manufacture, use, or sale of drugs and also clearly regulates the manufacture, use or sale of medical devices. Thus, the use of a patented invention for the development and submission of information concerning medical devices required by the FDCA is not an act of infringement.

Allowing a patent owner to prevent clinical trials of an improved medical device would discourage innovation. If this Court were to adopt Petitioner's statutory construction of section 271(e), the holder of a patent on a roughly-conceived²

² Roughly conceived insofar as there is no working prototype until ten years after the patent issues.

medical device could subject the invention to five years of clinical trials, obtain a five-year extension to the original seventeen-year patent, and then prevent competitors from clinically testing an improvement until the end of the extended term, some twenty-two years from the issue date of the patent. Clinical trials of improved, lifesaving devices by would-be competitors might take five more years, effectively rendering the next generation of medical devices commercially unavailable to the public for twenty-seven years after the issuance of the original patent.³

The fast developing world of medical technology requires investment in new companies that are willing to innovate. However, a new company founded on improving a patented medical device would find it very difficult to function if it could not clinically test its improved medical device until after the extended term of the dominant patent had expired. This would significantly discourage innovation as investment would be stifled.

Petitioner's contention that section 271(e)(1) was enacted to immunize the testing of generic drugs bypasses the fact, not disputed by Petitioner, that the statute also immunizes the testing of improved drugs which are *not* generic or bioequivalent. Improved drugs, which are still covered by patent, may have properties that are far superior to the patented drug that is being marketed by the patent owner. Clinical trials of the improved drug, which may take sales away from the patented drug, are required by the FDA and are indisputably immunized by section 271(e)(1). Likewise, improved medical devices, which are covered by a dominant medical device patent but which may have far superior capabilities, are contended by Petitioner as not being immunized from infringement by section 271(e)(1). As a matter

³ The rapid advances in medical technology continually decrease the period of time between each successive generation of new devices.

of public policy and simple logic, there is no rational reason for Congress to have immunized the testing of improved drugs under section 271(e)(1) while permitting the patent owner to prevent clinical trials of improved medical devices. Petitioner's argument is particularly disingenuous in view of the congressional grant of extended patent terms for improved drug and medical devices based on the clinical trials required for both. 35 U.S.C. § 156 (1984).

ARGUMENT

I. Exempting The Clinical Testing Of Improved Medical Devices From Patent Infringement Under Section 271(e)(1) Is In The Public Interest.

A. The Public Interest Is Served By Placing Improved Medical Devices Before The Public.

Providing the public with an improved lifesaving medical device is obviously in the best interest of society. The superiority of Ventrinetex's defibrillator over the Lilly CPI defibrillator is readily apparent. Lilly's defibrillator does nothing more than provide a high energy shock to deliver a rapidly beating heart back to normal sinus rhythm.⁴ In contrast, Ventrinetex's defibrillator also treats tachycardia and bradycardia with pacemaker therapy having a much lower energy level. Pacemaker therapy provides little or no discomfort to the patient, in contrast to the pain concomitant with the much higher energy shocks from Lilly's defibrillator.

For patients who need pacing as well as defibrillation, Lilly requires that two separate units, with separate leads, be implanted. Worse yet, the implanted units may interfere with the operation of each other (JA51, 75).⁵ On the other

⁴ Abnormal heart rhythm, or arrhythmia, includes fibrillation (fluttering of the heart), tachycardia (abnormally fast heartbeat), and bradycardia (abnormally slow heartbeat).

⁵ "JA" refers to the designated pages of the Joint Appendix filed with Petitioner's Brief.

hand, the implantable defibrillators manufactured by Ventrinetex are superior in that they combine (1) a pacemaker to detect and treat bradycardia and tachycardia and (2) a defibrillator, in a single unit. The pacemaker and defibrillator functions are effectively integrated to support each other.

Lilly plainly seeks to have this Court construe section 271(e)(1) so that companies such as Ventrinetex cannot even clinically test these superior devices during the extended period of Lilly's patent in order to provide these lifesaving devices to the public as soon as possible after Lilly's patent expires. Lilly's construction would divert the resources of a new company into defending an expensive lawsuit instead of enabling the company to direct its resources into obtaining FDA approval of its improved medical device.

Beyond the overriding public interest in getting lifesaving devices before the public, the sooner the improved medical device can be commercialized, the sooner investors will see a return on their investment making them more likely to invest in a new company such as Ventrinetex. Investment in start-up companies which intend to develop improved medical devices is significant to the economic and physical health of this country, benefiting not only the investors but also the public at large. There is a need to foster the revival of the entrepreneurial spirit in order to compete in this global economy. Investments in new companies, which have the personnel and desire to develop and produce an improved device, must be encouraged.

B. FDA Control Of Medical Device Clinicals And Section 271(e) Work In Harmony To Protect The Public Interest And Lilly.

Lilly complains that it would lose significant business during clinical testing of infringing improvements by others. The record proves otherwise (JA31, 106, 114). Clinical testing is strictly regulated by the FDA (21 C.F.R., Part 812;

JA143-53). Careful and detailed records must be maintained (21 C.F.R. § 812.140). There can be no commercialization of the device during clinical testing (21 C.F.R. § 812.7). The number of implantable devices and the number of investigators is limited (21 C.F.R. § 812.25, § 812.43). The number of patients whom the investigators can treat is limited (21 C.F.R. § 812.25). The device cannot be commercialized by charging a price larger than that necessary to recover costs of manufacture, research, development, and handling (21 C.F.R. § 812.7(b)). The clinical testing cannot be unduly prolonged (21 C.F.R. § 812.7(c)). Thus, the manufacturer would not be able to extend its clinical testing of the device over an extraordinary period of time in order to avoid infringement.

The language of section 271(e) immunizes the manufacturer from infringement only if the patented invention is made, used or sold "solely for uses reasonably related to the development and submission of . . . [I.D.E.] information." If a manufacturer were abusing the clinical trial immunity, the manufacturer's acts would not be "solely for uses reasonably related to the development and submission of . . . [I.D.E.] information." See, e.g., *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379, 1395-97 (N.D. Cal. 1987), modified on other grounds, 678 F. Supp. 1429 (N.D. Cal. 1988), summary judgment granted, 707 F. Supp. 1547 (N.D. Cal. 1989); *American Standard Inc. v. Pfizer Inc.*, 722 F. Supp. 86 (D. Del. 1989).

It has been suggested on page 31, n.21 of Petitioner's brief that clinical trials in the United States may be unnecessary because the start-up company could perform clinical trials of the device overseas to avoid infringement. This suggestion is meritless and impractical with respect to a start-up company. First, in order to avoid infringement if 271(e)(1) did not cover devices, a company would also have to *manufacture* the device overseas. Second, in order to manufacture overseas,

a company would require an overseas factory, equipment, training of foreign personnel, and components which must be made overseas. The company would need facilities which duplicate its United States facilities, requiring extraordinary expense. Since it is difficult enough for a start-up company to survive, the additional expense required to support an overseas manufacturing operation would be devastating. The benefits to this country of having the production facilities located here, where United States workers are employed and where the components are purchased, are obvious.

II. The Public Interest Is Not Served By Lilly's Construction Of Section 271(e)(1).

It would be contrary to public policy for the statute to be construed to provide an infringement exception for the clinical trials of pharmaceutical drugs but not for the clinical trials of medical devices. Medical devices are constantly being improved. Lilly obtained the significant advantage of two years of patent term restoration (35 U.S.C. § 156) for the clinical testing of its defibrillator. Now Lilly maintains that its potential competitors cannot clinically test their defibrillators until Lilly's patent term extension expires. The specific facts of the instant case show the inequity and illogical nature of Lilly's contention.

Lilly's predecessor-in-interest filed the patent application on the implantable defibrillator in 1967. At that time, the defibrillator was merely a concept—there was no useful operable device. The patent issued in 1971. It was not until 1980 that the first human implant occurred and not until 1985 that the FDA approved the defibrillator for commercial use. During the time period from the patent's issuance in 1970 and the approval for commercialization in 1985, Lilly's predecessor-in-interest had full patent rights. The patent rights include the right to prevent others from making, using or selling the invention. However, others could have, and did, develop a superior device. Although Lilly's patent would

normally have expired in 1988, as a result of the Patent Term Restoration Act, 35 U.S.C. § 156, Lilly was able to obtain a two-year patent extension. The patent will not terminate until 1990. During the 1971-1990 patent term, there was much time for other companies to develop improved implantable defibrillators. Yet, these improved defibrillators cannot be commercialized because they have not been approved by the FDA.

Clinical testing of Ventrifex's defibrillator began in July of 1989, during the extended period of the Lilly patent. There is no possibility that the clinical trials will be concluded and that its device will receive FDA approval prior to the expiration of the Lilly patent. However, Lilly urges this Court to construe section 271(e)(1) so that the clinical trials, which are required for FDA approval and eventual commercialization of the device, constitute patent infringement. Notwithstanding the two-year extension obtained by Lilly, Lilly expects all potential competitors to wait until Lilly's patent has expired before commencing clinical trials, thereby giving Lilly an effective patent term for preventing commercialization by others that is substantially greater than the nineteen-year term that it was granted. Thus, Lilly seeks to benefit from an additional extension to the section 156 extension that it has already received. This is contrary to what Congress intended in passing section 271(e)(1).

III. No Logical Differentiation Exists Between Improved Medical Devices And Improved Drugs.

No logical reason permits differentiation between an improved medical device and an improved drug. Indeed Lilly cannot deny that section 271(e)(1) immunizes clinical testing of an improved drug from patent infringement.⁶ On pages 28-30 of its brief, Petitioner contends that there are

⁶ Lilly concedes that section 271(e)(1) "also permit[s] clinical trials of patented drugs...". Pet. Brief at page 30 n.2.

important distinctions between FDA regulation of drugs and medical devices. These apparent distinctions, however, only apply to generic drugs. They do not apply to improved drugs. An improved drug is one that is covered by a dominant patent, but is not marketed by the patentee. The improved drug has properties that are different enough from the patent owner's FDA-approved drug that it is not bioequivalent and, thus, requires full clinical testing.

For example, assume that pharmaceutical company 1 obtains a patent on an anticoagulant drug having a composition of elements A, B and C, and company 1 successfully markets the drug after clinical trials and FDA approval. Then competitor 2 develops an anticoagulant drug which is greatly superior to company 1's drug, but company 2's drug contains a composition of elements A, B, C and D. Company 2's drug is not bioequivalent to company 1's drug and full clinical trials are required for FDA approval. Company 2 would be able to engage in such clinical trials because it is excused from patent infringement under section 271(e), even though company 1's patent covers company 2's improved drug.

Now assume that company 1 owns a patent on a medical device for treating cardiac patients, with the device comprising a combination of elements E, F and G. During the patent term, company 3 develops a greatly superior medical device, comprising elements E, F, G, H and I. Since the superior medical device is not identical to the medical device being marketed by company 1 that is FDA approved, company 3's medical device will have to be clinically tested for FDA approval. There is absolutely no reason why company 2's drug should be immune from patent infringement while company 3's medical device should not be immune from patent infringement. Contrary to Lilly's contention on page 30 of its brief, the "abbreviated procedure for pre-market approval" does not apply to either the improved drug or to the improved medical device, yet the improved drug is

indisputably immune from patent infringement during clinical trials. Thus, Lilly's argument concerning limited bio-equivalence testing is totally inapplicable to improved drugs, which fall within the section 271(e)(1) exception.

Further, just as the clinical testing of the medical devices may render certain patients unavailable as customers to the patent owner, the clinical testing of the improved drug may also render patients using that drug during clinical trials to be unavailable as customers to the patent owner. Lilly's contention, on page 31 of its brief, that the clinical trials could "rob patent holders" in lost sales is frivolous in view of the added years to the patent resulting from 35 U.S.C. § 156. A competitor could just as easily state that the extended period of time that Congress has allowed to be added to drug and medical device patents "robs" competitors in lost sales of improved drugs and improved medical devices.

CONCLUSION

For the foregoing reasons *amicus* Ventritex submits that the judgment of the Court of Appeals for the Federal Circuit should be affirmed.

Respectfully submitted,

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